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10/616,251

07/08/2003

Peter Martin

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JOHN R. ROSS
Trex Enterprises
10455 Pacific Center Ct.
San Diego, CA 92121

EXAMINER

YANG, NELSON C

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

05/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/616,251

Applicant(s)

MARTIN ET AL.

Examiner

Nelson Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 6,18-20,27 and 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-17,21-26,28-30 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1-5, 7-17, 21-26, 28-30, 38-44 are currently under examination
2. Claims 6, 18-20, 27, 31-37 have been withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 7-9, 12-17, 26, 28-30, 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. [US 6,970,239] in view of Iwasaki et al. [US 2002/0109134].

With respect to claims 1, 38, 41, 42, Chan et al. teach a porous silicon substrate (column 6, lines 45-50), wherein the microfluidic channels (buffer-sample fluid flow channel) may be etched in the substrate (column 6, lines 1-6). Chan et al. further teach Raman detectors (spectral monitor) (column 9, lines 45-55), light sources such as lasers and light emitting diodes (column 10, lines 24-30), as well as computers coupled to the Raman detection units for storing and comparing emission profiles from analytes (column 11, lines 60-67) and micro-electro-mechanical systems for controlling the pumps and valves (fluid flow control system, column 8, lines 20-37). Chan et al. further teach that the size and shape of the pore size in porous silicon may be selected to be within

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predetermined limits to optimize optical phenomenon such as plasmon resonant frequency (column 4, lines 20-25). Chan et al. fail to teach that the depth of the pores is at least 10 times larger than the width of the pores, with the depth approximately equal to the depths of the other pores. The bottom surface is approximately parallel to the top surface of the substrate (fig. 2).

Iwasaki et al., however, teaches pores with depths of 10 nm to 100 μm (para. 0052) and diameters of several nm to several hundreds nm (para. 0050), thus creating pores where the depth of the pores is at least 10 times larger than the width of the pores, and teaches that this allows for a high degree of light control (para. 0014). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, the reference discloses the general teachings of the claims, including that the Raman sensitive metal coated on porous silicon and that the pore size can be varied to optimize optical phenomena such as surface plasmon resonant frequency (column 4, lines 15-25). Thus, providing a pore which has a depth and width, with a relative depth and width as claimed by Applicant would be recognized by one of ordinary skill in the art, as shown by Iwasaki et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have pores where the depth of the pores is at least 10 times larger than the width of the pores in the invention of Chan et al., as suggested by Iwasaki et al., in order to obtain a high degree of light control, by utilizing optimization techniques known to one of ordinary skill in the art.

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5. With respect to claim 2, Chan et al. teach a porous silicon substrate (column 6, lines 45-50), wherein the microfluidic channels (plurality of channels) may be etched in the substrate (column 6, lines 1-6). Chan et al. further teach photodiode arrays (column 10, lines 44-46), which would comprise multiple photodiodes (plurality of light sources), as well as one or more Raman detection units (plurality of spectral monitors) (column 9, lines 50-55).

6. With respect to claims 3 and 43, although Chan et al. do not teach at least four porous silicon regions, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, it would have been obvious to one of ordinary skill in the art to have at least four porous regions in the invention of Chan et al. through normal optimization procedures known in the art.

7. With respect to claims 4, 28, the Raman detection units and computers (column 9, lines 45-44; column 11, lines 60-67) taught by Chan et al. would be capable of making kinetic molecular binding measurements.

8. With respect to claims 5 and 44, Chan et al. teach a spectrometer (claim 14).

9. With respect to claim 7, Chan et al. teach a porous silicon substrate (column 8, lines 20-23). Therefore, the porous silicon would be located on a silicon substrate, as it is part of the substrate.

10. With respect to claim 8, Chan et al. teach a p-doped silicon (column 12, lines 44-47) and may comprise a single crystal silicon wafer (column 12, lines 50-55).

11. With respect to claim 9, Chan et al. teach a porous silicon substrate (column 6, lines 45-50), wherein the microfluidic channels (buffer-sample fluid flow channel) may

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be etched in the substrate (column 6, lines 1-6). Chan et al. further teach valves to control the function of the MEMS (column 8, lines 35-38).

12. With respect to claim 12, although Chan et al. do not teach pores with nominal widths of 80 to 120 nm and nominal depths of 1000 to 3000 nm, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, it would have been obvious to one of ordinary skill in the art to have pores with nominal widths of 80 to 120 nm and nominal depths of 1000 to 3000 nm in the invention of Chan et al. through normal optimization procedures known in the art.

13. With respect to claim 13, Chan et al. teach a chamber (cartridge) may be cut out of a silicon wafer and incorporated into a chip or other device (fluidics enclosure) (column 1-6).

14. With respect to claim 14, Chan et al. teach charged injection devices (column 10, lines 43-45), which would be capable of injecting samples into a fluidics enclosure.

15. With respect to claims 15-16, Chan et al. teach components such as pumps (which would be capable of being sample and buffer pumps), valves, heaters, coolers, filters, control actuator components (pneumatic controls) (column 8, lines 30-37). Chan et al. further teach that the substrate may be connected to various fluid filled compartments (column 60-65), of which these compartments would be capable of being waste tanks, buffer fluid tanks. Chan et al. further teach computers coupled to the Raman detection units for storing and comparing emission profiles from analytes (column 11, lines 60-67)

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and micro-electro-mechanical systems for controlling the pumps and valves (fluid flow control system, column 8, lines 20-37).

16. With respect to claim 17, Chan et al. teach light emitting diodes (column 10, lines 24-30), which would be capable of delivering white light (white light source).

17. With respect to claims 26 and 40 the Raman detection units and computers taught by Chan et al. are capable analyzing and comprising emission profiles for standard analytes (column 9, lines 45-44; column 11, lines 60-67) and would therefore be able to at least indirectly calculate changes in apparent optical path differences (in order to determine the identity of the analytes in the sample) and determine the values of rate constant k_{on} and k_{off} .

18. With respect to claim 29, although Chan et al. do not teach pores with nominal widths chosen to produce a modulation index for optimizing optical resolution, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, it would have been obvious to one of ordinary skill in the art to have pores with nominal widths of 80 to 120 nm and nominal depths of 1000 to 3000 nm in the invention of Chan et al. through normal optimization procedures known in the art.

19. With respect to claim 30, although Chan et al. do not teach pores with nominal widths chosen to produce a modulation index for optimizing kinetic binding assays, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re*

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Aller, 105 USPQ 233. Therefore, it would have been obvious to one of ordinary skill in the art to have pores with nominal widths chosen to produce a modulation index for optimizing kinetic binding assays in the invention of Chan et al. through normal optimization procedures known in the art.

20. With respect to claim 39, Chan et al. teach graph forming means (spectrographs (column 10, lines 40-46), which are capable of producing a graph of OPD vs. time.

21. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. [US 6,970,239] in view of Iwasaki et al. [US 2002/0109134] and further in view of Gates [US 4,037,472].

With respect to claims 10 and 11, Chan et al. teach a porous silicon substrate (column 6, lines 45-50), wherein the microfluidic channels (buffer-sample fluid flow channel) may be etched in the substrate (column 6, lines 1-6). Chan et al. further teach Raman detectors (spectral monitor) (column 9, lines 45-55), light sources such as lasers and light emitting diodes (column 10, lines 24-30), as well as computers coupled to the Raman detection units for storing and comparing emission profiles from analytes (column 11, lines 60-67) and micro-electro-mechanical systems for controlling the pumps and valves (fluid flow control system, column 8, lines 20-37). Chan et al. fail to specifically teach the use of pinch valves.

Gates, however, teach that a particular advantage of pinch valves is that it is less likely to become clogged by suspended solid materials in the samples being drained, than would any valve of conventional design (column 3, lines 15-35).

Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to use pinch valves, as the pinch valves would be less likely to become clogged by suspended solid materials in the samples being drained.

22. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. [US 6,970,239] in view of Iwasaki et al. [US 2002/0109134] and further in view of Virtanen [US 6,342,349].

With respect to claims 21-23, Chan et al. teach linker groups comprising polytetrafluoroethylene, polyvinyl pyrrolidone, polystyrene, polypropylene, polyacrylamide, polyethylene or other known polymers silanes, alkanes, derivatized silanes or derivatized alkanes (column 8, lines 5-17), which one of ordinary skill in the art would realize would include PEG and other carboxylic acid containing molecules.

Virtanen further teaches the use of BIO-PEG-carboxylic acid for use as a cleavable spacer capable of recognizing IgG (column 71-72, example 2).

Therefore, since Chan et al. provides motivation for utilizing different linker groups for binding different species, one of ordinary skill in the art at the time of the invention would have been motivated to specifically use a carboxylic acid containing PEG molecule to functionalize the pores, in order bind antibodies such as IgG, that are also cleavable spacers.

With respect to claims 24-25, although neither Chan et al. nor Virtanen teach PEG molecules comprising four monomers with a total length of 19.2 Angstroms, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re*

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Aller, 105 USPQ 233. Therefore, it would have been obvious to one of ordinary skill in the art to have PEG molecules comprising four monomers with a total length of 19.2 Angstroms through normal optimization procedures known in the art.

Response to Arguments

23. Applicant's arguments filed March 2, 2007 have been fully considered but they are not persuasive.

24. In response to applicant's argument that the invention is directed toward Raman spectroscopy and does not suggest a sensor for making measurements based on changes in spectral interference patterns, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this situation, the Office notes that one of ordinary skill in the art would realize that Raman spectroscopy takes spectral data obtained from the interference patterns as seen on p.9208, col.2 of Dudovich et al. [Dudovich et al., Single-pulse coherent anti-stokes raman spectroscopy in the fingerprint spectral region, May 2003, J Chem Phys, 118(20) p.9208-9215] and column 5, lines 20-30 of Alfano et al. [US 5,293,872]. The Office further notes that applicants themselves recite spectral monitors configured to monitor Ramon scattering.

25. For these reasons, applicant's arguments are not found persuasive.

Conclusion

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26. No claims are allowed.

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641


LONG V. LE 05/23/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600